35

WO 00/12064 PCT/US99/19847

Claims:

1. A stable pharmaceutical composition of meprazole for oral administration which consists essentially of:

- (a) a core of Omeprazole or a pharmaceutically equivalent salt, a filler and an alkaline material selected from the group consisting of lysine and arginine; and
- (b) a single layer of coating on said core which10 comprises a layer of an enteric coating agent applied from an organic solvent based system.
 - 2. A pharmaceutical composition of omeprazole as defined in claim 1 wherein said core is further () comprised essentially of a surface active agent, and a binder and said pharmaceutical composition is formed into a compressed tablet.
- 3. A pharmaceutical composition as defined in claim 1
 wherein said core is further comprised essentially of a an inert core component, a surface active agent and a binder and said pharmaceutical composition is pelleted.
- 4. A pharmaceutical composition of omeprazole as
 defined in claim 2 wherein the acid resistant component
 is selected from the group consisting of cellulose
 acetate phthalate, hydroxypropylmethyl cellulose
 phthalate, polyvinyl acetate phthalate,
 carboxymethylethylcellulose, co-polymerized methacrylic
 acid/methacrylic acid methyl esters.
 - 5. A pharmaceutical composition of omeprazole as defined in claim 3 wherein the acid resistant component is selected from the group consisting of cellulose acetate phthalate, hydroxypropylmethyl cellulose phthalate, polyvinyl acetate phthalate,

carboxymethylethylcellulose, co-polymerized methacrylic acid/methacrylic acid methyl esters.

- 6. A pharmaceutical composition of omeprazole as defined in claim 1 wherein the enterio coating agent also includes an inert processing aid.
- 7. A pharmaceutical composition of omeprazole as defined in claim 1 wherein the enteric coating agent around the core includes from 5 to 55wt% by weight of the coating of an inert processing aid.
- 8. A pharmaceutical composition of omeprazole as defined in claim 1 which includes a sodium lauryl sulfate as the surface agent.
 - 9. A pharmaceutical dosage formulation which consists essentially of:
- (a) a tablet core comprising omeprazole, a binder, an alkaline agent selected from the group consisting of arginine or lysing a filler; and
 (b) an enteric coating agent around said core, said enteric coating agentising hydroxypropylmethyl

cellulose phthalate and talc.

25

- A pharmaceutical composition as defined in claim 3 wherein the core contains a non-pariel sugar seed.
- 11. A pelleted pharmaceutical dosage formulation which consists essentially of:
 - (a) a core comprising a non-pariel sugar seed coated with drug layer composition comprising omeprazole, a binder, an alkaline agent selected from the list consisting of arginine and lysine, a filler and a surface active agent; and
 - (b) In enteric coating agent around said core, said

35

WO 00/12064 PCT/US99/19847

enteric coating comprising hydroxypropylmethyl cellulose phthalate and talc which is applied from an organic solvent based system.